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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/536,467

05/25/2005

Sergei Braun

29948

4946

7590

02/21/2008

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EXAMINER

MESH, GENNADIY

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

02/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/536,467	Applicant(s) BRAUN, SERGEI	
	Examiner GENNADIY MESH	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 114- 152 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 132-144 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/20/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Claims 132 – 144 in the reply filed on November 13, 2007 is acknowledged.

Claims 113 -131 and 145 – 152 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 1 – 112 are canceled by Applicant.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 132-144 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for general method of treatment of protein contain substances in order to obtain promoters and following step of polycondensation of those promoters, does not reasonably provide enablement for polymers with structures claimed by Applicant in Claims 132-144. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope of claims 132-144.

Case law holds that applicant's specification must be "commensurately enabling [regarding the scope of the claims]." See *Ex Parte Kung*, 17 USPQ2d 1545, 1547 (Bd. Pat. Appl. Inter. 1989). Otherwise **undue experimentation** would be involved in

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determining how to practice and use applicant's invention. The test for undue experimentation as to whether or not all compounds within the scope of claims 132-144 can be used as claimed and whether claims 132-144 are meet the test is stated in *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. Appl. Inter. 1986) and *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Upon applying this test to claims 132-144 , it is believed that undue experimentation **would** be required because:

(a) *The quantity of experimentation necessary* is **great** since claims 132 -144 read on very wide variety of compounds containing natural modified or not modified amino acids.

(b) There is **no direction or guidance presented** for making **specific** polymers with specific **polymer structures** as claimed in Claims 1342-144.

(c) There is an **absence of working examples** concerning making and **isolating specific polymers** with structures as it claimed in Claims 132-144.

In light of the above factors, it is seen that **undue experimentation would be necessary** to make and use the invention of claims 132-144.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 132 – 144 are rejected under 35 U.S.C. 102(b) as being unpatentable over Goodman et al.(US Re. 30,170) in view of Gouesnard “ Reactivite du nitrite de sodium. V. Action sur les amino-acides, peptides et proteines” *BULLETIN DE LA SOCIETE CHIMIQUE DE FRANCE* 1989 N° 1 – cited by Applicant.

Goodman discloses hydrolysable copolymers of natural amino acids and hydroxyacids obtain by incorporation of alpha (or beta or gamma) hydroxyacids residue in peptide backbone (see abstract and column 1, lines 12-18), wherein amino acid and hydroxyacid linked by ester bond (see Goodman , general formula on bottom of column 1 and in the top of column 2) – same as it require by A-B bond of radicals A and B in Claims 132 -144. According to Goodman (see column4,lines 15-25) presence of ester bond “to endow it (polymers) with the desirable hydrolysable properties”.

Radical A as $Y-CO-CHR_a-O\cdot$ reads on hydroxyacids residue when R_a is hydrogen and Y is OH group and residue of natural amino acid (in general formula provided by Goodman) reads on radical B - note, that peptide backbone comprising all natural occurring amino acids claimed as radical B by Applicant.

Goodman is silent regarding use of specific radicals A (different from $Y-CO-CHR_a-O$) as a residue of **hydroxy amino acids** (see for example structure in Claim 135).

However, Gouesnard teach that hydroxyl amino acids can be obtain by treating proteins with sodium nitrite (see Scheme 1, page 89).

Therefore, it would be obvious to one of ordinary skill in the art to use hydroxy amino acids obtained per teaching of Gouesnard in stead of hydroxyacids in order to prepare hydrolysable polyesters as it disclosed by Goodman with reasonable expectation of success, until unexpected results to the contrary can be shown by Applicant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GENNADIY MESH whose telephone number is (571)272-2901. The examiner can normally be reached on 10 a.m - 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272 1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner
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GM

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Supervisory Patent Examiner, Art Unit 1796